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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,118	10/15/2003	Paul R. Hinton	011823-012610US	7362

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EXAMINER	
CROWDER, CHUN	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/687,118	HINTON ET AL.	
	Examiner	Art Unit	
	Chun Crowder	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05/02/2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6,8-12,15-21,23-28,31-43,49,52-54,57-64 and 67-69* is/are pending in the application.

4a) Of the above claim(s) *15-17,31-33,54,57-64 and 67-69* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5, 6, 8-12, 18-21, 23-28, 34-43, 49, 52, and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 05/02/2006, has been entered.

Claims 4, 7, 13, 14, 22, 29, 30, 44-48, 50, 51, 55, 56, 65, 66 have been canceled.

Claims 1, 5, 6, 8-12, 15-17, 19, 24-27, 30-43, 49, 52, 53, 57-58, 60-64, 67-69 have been amended.

Claims 1-3, 5, 6, 8-12, 15-21, 23-28, 31-43, 49, 52-54, 57-64, and 67-69 are pending.

Claims 15-17, 31-33, 54, 57-64, and 67-69 have been withdrawn from consideration by the Examiner, under 37 C.F.R. 1.142(b), as being drawn to nonelected inventions.

Claims 1-3, 5, 6, 8-12, 18-21, 23-28, 34-43, 49, 52, and 53 are currently under consideration as they read on original elected species of amino acid substitutions at positions 250 and 428, with amino acid residues glutamine and leucine, respectively.

2. The text of those sections of Title 35 U.S.C. not included in this Action can be found in a prior Action.

This Office Action will be in response to applicant's amendment, filed 05/02/2006.

The rejections of record can be found in the previous Office Action, mailed 12/13/2005.

3. It is noted that the Restriction Requirement including Species Election is maintained for reasons of record set forth in the Office Action, mailed 09/20/2005.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

4. The applicant's request for rejoinder rules is acknowledged.

5. Claims 1, 8-12, 18, 19, 24-28, 34-43, 49, 52, and 53 stand rejected under **35 U.S.C. 102(b)** as being anticipated by Martin et al. (Molecular Cell, 2001, 7:867-877) (see entire document) as evidenced by Hinton et al. (JBC, 2004, 279;(8):6213-6216) (see entire document).

Applicant's arguments, filed 05/02/2006, have been fully considered but have not been found convincing.

Applicant argues that reference of Hinton et al. is post filing date reference therefore cannot serve as basis for rejection under 35 U.S.C. 102(b). Further, applicant asserts that Martin et al. do not teach amino acid substitutions with specific residues and that Martin et al. teaches only rat Fc fragment without any variable regions and do not teach any fragment of a human antibody.

This is not found persuasive for the following reasons:

Contrary to applicant's assertion, Martin et al. teach the mechanisms of pH-dependent binding between an FcRn and heterodimeric Fc complex using the crystal structure of rat Fc/FcRn as a model which can be used to guide rational design of the

therapeutic IgGs with longer serum half-life (see entire document, particularly the Title and the Abstract).

Martin et al. further teach general strategy for identification of Fc mutants with increased affinity for FcRn and that residues include 250 in the Fc region are good candidates for making mutants with increased affinity for FcRn; an approach involving random substitutions at these positions can yield further increases in binding to FcRn (e.g. see page 874, in particular). Furthermore, Martin et al. teach a mutagenesis strategy involving positions 428 with amino acid residues with hydrophobic side chains can result in stabilization of the interaction of Fc/FcRn and therefore increase Fc binding to FcRn. It is well known in the art at the time the invention was made, as well as evidenced by Hinton et al. that leucine is one of the hydrophobic amino acid residues (see entire document, particularly page 6214).

Regarding Hinton et al. being post-filing date reference, it is noted that a specification must be enabling as of the filing date. It is noted that post-filing date references can be used as evidence of the state of the art existing on the filing date of the application. See MPEP 2164.05(a).

Extra reference or evidence can be used to show an inherent characteristic of the thing taught by the primary reference. As long as there is evidence of record establishing inherency, failure of those skilled in the art to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not preclude a finding of anticipation. See MPEP 2131.01 III.

Thus, it is appropriate to include Hinton et al. as evidentiary reference in rejections under 35 U.S.C. 102.

It is further noted that claims 1, 8-12, 18, 19, 24-28, 34-43, 49, 52, and 53 do not recite "human antibody".

Therefore, the reference teachings anticipate the claimed invention.

The rejections of record are maintained for the reasons of record, as they apply to the amended claims. The rejections of record are incorporated by reference herein as if reiterated in full.

6. Claims 1, 2, 3, 5, 6, 20, 21, and 23 stand rejected under **35 U.S.C. 103(a)** as being unpatentable over Martin et al. (Molecular Cell, 2001, 7:867-877) (see entire document) in view of Reff et al. (Critical Review in Oncology/Hematology, 2001, 40:25-35) and Ogata et al (PNAS, 1993, 90:3014-3018) for reasons of record set forth in the Office Action mailed 12/13/2005.

Applicant's arguments, filed 05/02/2006, have been fully considered but have not been found convincing.

Applicant argues that no *prima facie* case of obviousness has been presented, and that Martin et al. merely provide hope of modification that may yield increased FcRn binding.

This is not found persuasive for following reasons:

The teachings of Martin el al. have been discussed, supra, and clearly teach the mechanisms of pH-dependent binding between an FcRn and heterodimeric Fc complex using the crystal structure of rat Fc/FcRn as a model which can be used to guide rational design of the therapeutic IgGs with longer serum half-life (see entire document, particularly the Title and the Abstract).

In considering the disclosure of a reference, it is proper to take into account not only specific teaching of the reference but also the inferences which one skilled in the art would be reasonably be expected to draw therefrom In re Preda, 401 F.2d 825, 159 USPQ 342, 344 (CCPA 1968). See MPEP 2144.01

Specific statements in the references themselves which would spell out the claimed invention are not necessary to show obviousness, since questions of obviousness involves not only what references expressly teach, but what they would collectively suggest to one of ordinary skill in the art. See CTS Corp. v. Electro Materials Corp. of America 202 USPQ 22 (DC SNY); and In re Burckel 201 USPQ 67 (CCPA). In re Burckel is cited in MPEP 716.02.

The motivation to combine can arise from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combine for their common known purpose. Section MPEP 2144.07.

Given the therapeutic implication of human monoclonal antibodies such as OST577 antibody in delaying infection of HBV and hepatitis in the chimpanzee (see entire document, particularly the Abstract and Results on pages 3015-3016) and the advantage of using human antibody in human therapy taught by Reff et al. (see entire document, particularly page 27), it would have been obvious to one of ordinary skill in the art at the time the invention was made to produce human OST577 antibody for potential therapeutic usage against HBV infection and to enhance its binding to FcRn by substituting amino acid at positions 250 and 428 of the Fc region for prolonged serum half-lives.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

7. Claims 1-3, 5, 8-10, 12, 19-21, 23-28, 34-43, 49, and 53 stand provisionally rejected on the ground of **nonstatutory obviousness-type double patenting** as being unpatentable over claims 1-8, 13 and 15 of copending USSN: 10/822,300.

This rejection is maintained until a terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) is timely filed.

8. Claims 1-3, 5, 8-10, 12, 18-21, 23-28, 34-43, 49, and 53 stand provisionally rejected on the ground of **nonstatutory obviousness-type double patenting** as being unpatentable over claims 1-5, 7-13, 15, 17-19 of copending USSN: 10/966,673.

This rejection is maintained until a terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) is timely filed.

9. Upon further consideration as well as applicant's amendment, the previous rejections under **35 U.S.C. 112, first and second paragraphs** have been withdrawn.

10. ***Conclusion: no claim is allowed.***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chun Crowder, Ph.D.
Patent Examiner
June 28, 2006

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PRIMARY EXAMINER
TC 1600
7/3/06